UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

IN RE: PLAVIX INDIRECT PURCHASER ANTITRUST LITIGATION

This Document Relates to: All Actions

Case No. 1:06–cv–226

Judge Michael H. Watson

OPINION AND ORDER

I. INTRODUCTION

This matter arises from actions against Defendant pharmaceutical manufacturers, Sanofi Aventis and Sanofi-Synthelabo, Inc. ("Sanofi Aventis") and Bristol-Myers Squibb Company and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership ("BMS") (collectively "Sanofi") and Apotex Corporation ("Apotex") (collectively "Defendants"). These cases involve Plavix, a pioneer clopidogrel bisulfate drug used to treat patients at risk for heart attacks and strokes. Sanofi manufacturers Plavix. Apotex was the first generic applicant to seek Federal Drug Administration ("FDA") approval to market a generic version of Plavix in the United States.

Claims are brought by the Indirect Purchaser Plaintiffs ("Plaintiffs") under the Clayton Act for injunctive relief, 15 U.S.C. § 26, and under state antitrust and consumer protection statutes. Plaintiffs assert Defendants' alleged illegal agreements prevented Defendants from entering into a legal competitive agreement which would have permitted the generic version of Plavix to enter the market at an earlier date and thus

allowed Plaintiffs to purchase the generic drug at a lower price. Plaintiffs claim that they have suffered damages as a result of Defendants' "anticompetitive conduct and scheme" which denied Plaintiffs "sustained market entry of less expensive, generic versions of Plavix" and required Plaintiffs to pay more for clopidogrel bisulfate drugs than they would have absent the anticompetitive conduct and scheme. End-Payor Plaintiffs' First Am. Consolidated Class Action Compl. 2, ECF No. 81 (hereinafter "Amended Complaint" or "Am. Compl.").

The Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337(a). This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367(a). This Court has jurisdiction over the putative class action pursuant to 28 U.S.C. § 1332(d)(2) which provides that district courts shall have original jurisdiction of any civil action in which the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, and is a class action in which "any member of a class of plaintiffs is a citizen of a State different from any defendant . . . ." 28 U.S.C. § 1332(d)(2)(A). Venue is proper in this Court pursuant to 15 U.S.C. § 22 because each Defendant transacts business here.

Defendants Sanofi and Apotex have moved the Court to dismiss the claims, pursuant to Fed. R. Civ. P. 12(b)(6), asserting that Plaintiffs have failed to allege the necessary elements of an antitrust action: a sufficient violation of antitrust laws and an antitrust injury. Defs.' Mots. Dismiss, ECF Nos. 87 & 88. For the reasons that appear below, Defendants' motions are **GRANTED**.

II. BACKGROUND

The Court's previous Opinion and Order sets forth the complete background,

facts, and parties to these cases, including an overview of the regulatory system governing the drug approval process, Apotex's ANDA and the patent litigation agreements between Sanofi and Apotex, and the generic drug launch by Apotex. *Kroger Co. v. Sanofi-Aventis*, 701 F. Supp. 2d 938 (S.D. Ohio 2010). The Court adopts and incorporates by reference that related Opinion and Order into this Opinion, specifically the findings regarding the absence of antitrust injury. *Id.* It is imperative to note that the basis of the claims in the cases *sub judice* are premised on the same alleged "injury" the Court disposed of in the aforementioned Opinion. Familiarity with that decision is presumed.

In this case, the Indirect Purchaser Plaintiffs' Amended Complaint alleges three causes of action: Count One seeks injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26; Count Two alleges a restraint of trade in violation of the antitrust and/or consumer protection statutes of the indirect purchaser states, including twenty-two states' laws and the District of Columbia; and Count Three alleges a claim for restitution, disgorgement, and constructive trust for unjust enrichment by Defendants.

The thrust of Plaintiffs' allegations is that but for Defendants entering into the March and May Agreements, Defendants would have instead entered into an agreement with terms more favorable to Plaintiffs. Plaintiffs claim Defendants would have either (1) entered into a licensing agreement granting Apotex a license to market its generic version of Plavix for a continuous and sustained period before the 2011 patent expiration date; or, alternatively (2) Sanofi would have given up some of its patent's life in exchange for delayed entry of Apotex's generic after Apotex received FDA approval. Plaintiffs allege either of these alternative allegedly procompetitive

agreements would have avoided the '265 patent trial and would have allowed Plaintiffs to receive the benefit of cost savings through generic competition.

III. STANDARD ON MOTION TO DISMISS

A claim survives a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) if it "contain[s] sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* A complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all of the complaint's allegations are true." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–56 (2007) (internal citations omitted).

A court must also "construe the complaint in the light most favorable to the plaintiff." *Inge v. Rock Fin. Corp.*, 281 F.3d 613, 619 (6th Cir. 2002). In doing so, however, plaintiff must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555; *see also Iqbal*, 129 S. Ct. at 1949 ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."); *Ass'n of Cleveland Fire Fighters v. City of Cleveland, Ohio*, 502 F.3d 545, 548 (6th Cir. 2007). Particularly in the antitrust context, the Supreme Court cautions that "a district court must retain the power to insist on some specificity in pleading before allowing a potentially massive factual controversy to proceed." *Mich. Division-Monument Builders of N. Am. v. Mich. Cemetery Ass'n*, 524 F.3d 726, 731–32 (6th Cir. 2008) (quoting *Twombly*, 550 U.S. at

558). The Supreme Court reminded lower courts that "it is one thing to be cautious before dismissing an antitrust complaint in advance of discovery, but quite another to forget that proceeding to antitrust discovery can be expensive." *Twombly*, 550 U.S. at 558 (internal citations omitted). "[A] naked assertion . . . gets the complaint close to stating a claim, but without some further factual enhancement it stops short of the line between possibility and plausibility . . . ." *Id.* Thus, "something beyond the mere possibility of [relief] must be alleged, lest a plaintiff with a largely groundless claim be allowed to take up the time of a number of other people, with the right to do so representing an in terrorem increment of the settlement value." *Id.* (internal citations omitted); *see also NicSand, Inc. v. 3M Co.*, 507 F.3d 442, 450 (6th Cir. 2007) (en banc).

IV. DISCUSSION

Defendants Sanofi and Apotex seek dismissal of all three of Plaintiffs' counts.

A. Count I: Injunctive Relief

Count I of Plaintiffs' Amended Complaint pleads a claim for injunctive relief under Section 16 of the Clayton Act for Defendants' alleged violations of Sections 1 and 2 of the Sherman Act. Am. Compl. ¶¶ 159–67. Defendants seek to dismiss Count I arguing that the Indirect Purchaser Plaintiffs lack standing to pursue a claim for injunctive relief because no threat of future injury or violation of the antitrust laws exists. Defendants claim that because Apotex launched at risk and was subsequently enjoined from the sale of generic clopidogrel bisulfate until the expiration of the patent, no circumstances exist in which injunctive relief would provide any further relief to Plaintiffs. Essentially, Defendants aver, there is nothing for the Court to enjoin. Furthermore, Defendants oppose Plaintiffs' attempts to obtain an injunction preventing the *practice* of entering

into reverse payment agreements claiming such injunction would be vague.

Plaintiffs seek to enjoin "Defendants from, directly or indirectly, entering an agreement to resolve or settle a patent infringement claim in which an ANDA filer receives a cash payment or anything of value in exchange for an agreement not to research, develop, manufacture, market, or sell the ANDA product for any period of time." *Id.* at ¶ 166. Plaintiffs state they are "threatened with future injuries as a result of collusive agreements that prevent or delay generic entry . . . ." *Id.* at ¶ 165. Plaintiffs assert the injunctive relief they seek is not specific to clopidogrel bisulfate, but instead is focused on the *practice* of entering into reverse payment agreements. Pls.' Memo Opp'n 9, ECF No. 94. Plaintiffs insist they incurred an antitrust injury as a result of the March and May agreements and that this economic injury from a lack of competition is the same type of future injury that is threatened by the *practice* of reverse payment agreements that they seek to enjoin. *Id.* at 10.

Section 16 of the Clayton Act, authorizing suits for injunctive relief, provides in part:

> Any person, firm, corporation, or association shall be entitled to sue for and have injunctive relief, in any court of the United States having jurisdiction over the parties, against threatened loss or damage by a violation of the antitrust laws, . . . when and under the same conditions and principles as injunctive relief against threatened conduct that will cause loss or damage is granted by courts of equity.

15 U.S.C. § 26.

A private party suing for damages or injunctive relief under the Clayton Act must demonstrate "antitrust standing." *Indeck Energy Servs., Inc. v. Consumers Energy Co.*, 250 F.3d 972, 976 (6th Cir. 2000), cert. denied, 533 U.S. 964 (2001). An antitrust

plaintiff seeking injunctive relief under Section 16 must allege a threatened antitrust injury, that is, injury of the type the antitrust laws were intended to prevent and that flows from that which makes a defendant's act unlawful. *See, e.g., Valley Products Co. v. Landmark*, 128 F.3d 398, 404 (6th Cir. 1997) (citing *Cargill, Inc. v. Monfort of Colorado, Inc.*, 479 U.S. 104, 111 (1986) ("[W]e conclude that in order to seek injunctive relief under § 16, a private plaintiff must allege threatened loss or damage of the type the antitrust laws were designed to prevent and that flows from that which makes defendants' acts unlawful.") (internal citations removed)); *see also In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395 (3d Cir. 2000) (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)).

A request for injunctive relief requires a showing of a "likelihood of substantial and immediate irreparable injury," a "requirement that cannot be met where there is no showing of any real or immediate threat that the plaintiff will be wronged again." *City of Los Angeles v. Lyons*, 461 U.S. 95, 103, 111 (1983); *see also Claybrooks v. Tenn. Dep't of Corrs.*, Case No. 98–6271, 1999 WL 503457, at *1 (6th Cir. 1999). "Abstract injury is not enough. The plaintiff must show that he 'has sustained or is immediately in danger of sustaining some direct injury' as the result of the challenged [] conduct and the injury or threat of injury must be both 'real and immediate,' not 'conjectural' or 'hypothetical.'" *Lyons*, 461 U.S. at 101–02. "Past exposure to illegal conduct does not in itself show a present case or controversy regarding injunctive relief . . . if unaccompanied by any continuing, present adverse effects." *O'Shea v. Littleton*, 414 U.S. 488, 495–96 (1974); *see also In re Nifedipine Antitrust Litig.*, 335 F. Supp. 2d 6, 17 (D.D.C. 2004). As the Supreme Court has observed, "[i]t would be anomalous . . . to

read the Clayton Act to authorize a private plaintiff to secure an injunction against a threatened injury for which he would not be entitled to compensation if the injury actually occurred." *Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. at 112.

Plaintiffs assert that the existence of the permanent injunction barring Apotex's generic entrance is not dispositive of the issue of whether Plaintiffs have standing to pursue injunctive relief since Plaintiffs request to enjoin the *practice* of entering so called reverse payment agreements. Essentially, Plaintiffs argue that they seek injunctive relief broader than the permanent injunction involving Plavix; they seek to enjoin any future collusive agreements by Defendants that might cause them injury. Am. Compl. ¶ 165.

The Court is not persuaded. While the Court agrees the existence of the permanent injunction barring Apotex's generic entrance might not be dispositive, it is relevant to the determination of whether "there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive." *U.S. v. W. T. Grant Co.*, 345 U.S. 629 (1953). The permanent injunction issued barring the sale of generic Plavix and the subsequent decision affirming it—and the subsequent denials to reexamine the validity of the patent by the USPTO—demonstrates that no additional injunctive relief is needed to protect Plaintiffs from collusive behavior by these Defendants in regard to Plavix. But Plaintiffs do not stop there.

Plaintiffs go so far as to request to enjoin Defendants from the possibility of entering into a yet-to-be-determined reverse payment agreement on some yet unidentified drug. The Court finds that too speculative a basis for injunctive relief. The

Court is not required to accept Plaintiffs' conclusions and inferences if they are unsupported by facts. Indeed, Plaintiffs provide no factual basis for their claims that there is any kind of threatened violation on the part of Defendants. While it has not escaped the Court's attention that BMS entered a plea agreement wherein it pleaded guilty to two counts of making false statements to government officials in connection with the proposed settlement, Plaintiffs merely speculate that Defendants' previous behavior and their status as the "world's leading" pharmaceutical or generic drug makers leads to the assumption that Defendants will engage in future collusive agreements. They stop short of alleging any actual imminent collusive agreement to protect a patent or drug. Based on the absence of facts alleged in the Amended Complaint and the speculative nature of Plaintiffs' remaining arguments regarding present and future harm, Plaintiffs simply have not established that there remains any "threatened conduct that will cause loss or damage" as necessary to seek injunctive relief. 15 U.S.C. § 26. Plaintiffs have failed to allege threatened loss or damage of the type the antitrust laws were designed to prevent and that flows from that which makes Defendants' acts unlawful. *See O'Shea*, 414 U.S. at 495–96. Accordingly, the Court denies Plaintiffs' request for injunctive relief and dismisses Count I.

B. Count II: Various States' Antitrust and Consumer Protection Statutes

Count Two of the Indirect Purchaser Plaintiffs' Complaint references claims for violations of various states' antitrust and consumer protection statutes. *See* Am. Compl. ¶¶ 168–71. The Amended Complaint says that Defendants' alleged anticompetitive agreements violated the antitrust and/or consumer protection statutes of the Indirect Purchaser States, including Arizona, Arkansas, California, District of

Columbia, Florida, Idaho, Iowa, Kansas, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin. *Id.* at ¶ 169, (a)–(bb). Plaintiffs seek "damages, multiple damages, treble damages, and other damages as permitted by state law . . . ." *Id.* at ¶ 170.

Defendants seek dismissal of Count Two arguing that the state law claims must be dismissed because, like the federal law claims and to the extent the state law claims are modeled after the Sherman Act, Plaintiffs' injury is hypothetical and caused by Apotex's lack of access to the valid patent and subsequent injunctions. Plaintiffs concede in their brief that "state courts are guided by federal law" and that the arguments brought by the Direct Purchasers regarding antitrust injury sufficient to state an antitrust claim under federal law are incorporated by the Indirect Purchasers as to their state law claims. See Pls.' Memo. Opp'n Mot. Dismiss at 21, ECF No. 94.

In these cases, like the Direct Purchasers' cases, the Indirect Purchaser Plaintiffs' alleged injury—paying "artificially inflated prices for Plavix"—derives from the lack of access to a generic substitute caused by the court-ordered injunctions barring sales of a generic because of Sanofi's valid patent and Apotex's lack of access or license to it. *Id.* at ¶ 164. To the extent a patent is valid—and the Federal Circuit has affirmed the validity of the '265 patent and the USPTO has repeatedly declined to re-review it—a patent lawfully excludes competition. The injury as Plaintiffs plead it, "being deprived of the ability to purchase less expensive, generic versions of Plavix" and therefore paying higher prices for name brand Plavix, does not stem from the

alleged anticompetitive behavior behind the March or May agreements. *Id.* at ¶ 170. Instead, the alleged "injury" is from the lawful patent and Apotex's lack of access to it—such "injury" is not of the type the antitrust laws were intended to prevent. Accordingly, since Plaintiffs fail to state a claim under the Sherman Act, and since the state antitrust claims are based on the same allegations, the state law claims are also dismissed. *See, e.g., Asahi Glass Co., Ltd. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 996 (N.D. Ill. 2003) (Posner, J.) ("the state antitrust charge falls for the same reasons as the federal, since there is no difference material to this case between the state and federal statutes") (citations omitted); *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 139 (E.D.N.Y. 2003) (since the plaintiffs failed "to state a claim under the Sherman Act, and since the [seventeen] state antitrust law claims are based on the same allegations, those claims are also dismissed"). *Cf.* Ariz. Rev. Stat. Ann. § 44-1412 and *Johnson v. Pacific Lighting Land Co.*, 817 F.2d 601, 604 (9th Cir. 1987), *cert. denied*, 484 U.S. 1062 (1988) (Arizona's antitrust law is interpreted in accordance with federal law.). Furthermore, Plaintiffs' consumer protection statute claims are premised wholly on the same underlying alleged anticompetitive behavior and antitrust injury. Thus the same result governs and the state unfair competition law claims are also dismissed. *See In re Tamoxifen*, 277 F. Supp. 2d at 139–40.

Additionally, the Court notes that Defendants oppose Plaintiffs' standing to assert claims in states without a connection to the individually named Plaintiffs, either because no named Plaintiff resided in the state or no Plavix was purchased in the state. Since the individually named Plaintiffs are located only in seven of the states with statutes that are cited, Defendants assert Plaintiffs cannot assert a nationwide class

action based on various individual states' antitrust laws because laws of one state cannot be applied to transactions occurring in another state. Thus, Defendants argue Plaintiffs lack standing to invoke the laws of those other states. Plaintiffs oppose such standing determination being decided prior to Rule 23 certification. Pls.' Memo Opp'n 14, ECF No. 94 (citing *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 831 ("class certification issues are . . . logically antecedent" to Article III concerns, . . . and themselves pertain to statutory standing, which may properly be treated before Article III standing. Thus the issue about Rule 23 certification should be treated first, "mindful that [the Rule's] requirements must be interpreted in keeping with Article III constraints . . . .") (internal citations omitted)).

The argument regarding if an injury was suffered by a named Plaintiff in each of the states alleged is of no moment. Even in states with a named Plaintiff or even if a nationwide class was certified, Plaintiffs' claims would still fail because the mandatory element of antitrust injury cannot be established as a matter of law. Accordingly, the viability of Apotex's argument that the Indirect Purchasers cannot bring a class action suit for state antitrust violations unless the named Plaintiff could personally pursue an individual claim under the antitrust laws of each applicable state need not be ruled upon by this Court.

C. Count III: Restitution, Disgorgement and Constructive Trust for Unjust Enrichment

Count III is a claim for restitution, disgorgement and constructive trust for unjust enrichment. Indirect Purchaser Plaintiffs request a constructive trust for the disgorgement of "anticompetitive sums indirectly [paid] to Defendants" based on the

supra-competitive prices for Plavix. *See* Am. Compl. ¶¶ 172–80.

The premise of the unjust enrichment claim hinges on, *inter alia*, a benefit conferred by a plaintiff upon a defendant. *See, e.g., Hambleton v. R.G. Barry Corp.*, 12 Ohio St. 3d 179 (1984) (to establish unjust enrichment under Ohio law, a plaintiff must demonstrate: "(1) a benefit conferred by a plaintiff upon a defendant; (2) knowledge by the defendant of the benefit; and (3) retention of the benefit by the defendant under circumstances where it would be unjust to do so without payment[.]").[1] As pleaded by the Indirect Purchaser Plaintiffs, Defendants have allegedly

> benefitted from unlawful agreements to allocate the entire United States clopidogrel bisulfate market to Sanofi and BMS, which agreements have enabled Sanofi and BMS to extract supra-competitive prices for Plavix, resulting in Plaintiffs' and the Class's payment and/or reimbursement of supra-competitive prices for Plavix.

Am. Compl. ¶ 173.

As this Court previously held in the Direct Purchasers case, Plaintiffs being "overcharged" on their purchases of this brand name drug resulted, not from the allegedly anticompetitive agreements, but rather, when the generic was pulled from the market as a result of the injunctions issued in the patent infringement action. The injunctions barring infringement of the '265 patent and the '265 patent itself are impenetrable legal impediments to the sale of generic Plavix, legally "enabl[ing] Sanofi and BMS to extract supra-competitive prices for Plavix." *Id.* Any payment by Indirect Purchasers for Plavix was not a "benefit conferred" but instead consideration for the patented drug.

---

[1]The Court notes the Amended Complaint does not reference any basis in law on which a claim for unjust enrichment might proceed. The Indirect Purchasers do not link their claim to the law of any particular state.

As such, the Indirect Purchaser Plaintiffs' unjust enrichment claim does not contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. *Iqbal*, 129 S. Ct. at 1949. The Court dismisses the Indirect Purchaser Plaintiffs' claim of unjust enrichment.

IV. CONCLUSION

Defendants' Motions to Dismiss are **GRANTED**. ECF Nos. 87 & 88, Case No. 1:06–cv–226. The Clerk is directed to close this case. The Clerk of Court is **DIRECTED** to enter final judgment with prejudice against Plaintiffs in the following cases and to close these cases: 1:06-cv-00227, 1:06-cv-00241, 1:06-cv-00257, 1:06-cv-00262, 1:06-cv-00281, 1:06-cv-00295, 1:06-cv-00339, 1:06-cv-00503, and 1:06-cv-00504. The Clerk is further instructed to remove all the aforementioned cases from this Court's Civil Justice Reform Act Report.

IT IS SO ORDERED.

MICHAEL H. WATSON, JUDGE
UNITED STATES DISTRICT COURT